Admn/Prop/35/2020-AIIMS.JDH Dated: - 14th September 2020.

Subject: Purchase of Continuous Renal Replacement Therapy Machine for the department of Pediatrics at AIIMS, Jodhpur on proprietary basis - **Inviting comments thereon.**

The Institute is in the purchase of Continuous Renal Replacement Therapy Machine for the department of Pediatrics at AIIMS, Jodhpur from M/s Baxter Gambro Lundia AB, Box 10101, Magistratsvagen 16, SE-220 10 Lund, Sweden on proprietary basis. The proposal submitted by M/s Baxter Gambro Lundia AB, Sweden and PAC certification by user are attached.

The above document are being uploaded for open information to submit objection, comments, if any from any manufacturer regarding proprietary nature of the equipment within 21days of issue giving reference Admn/Prop/35/2020-AIIMS.JDH. The comments should be received by office of Administrative Officer, Medical College at AIIMS, Jodhpur on or before 05th October 2020 upto 03:00 PM failing which it will be presumed that any other vendor is having no comment to offer and case will be decided on merits.

Yours faithfully,

Administrative Officer

Enclosed: Related documents enclosed.

Baxter

Gambro Lundia AB
Box 10101
Magistratsvägen 16
SE-220 10 Lund
Sweden

Date: 27th May 2019

PROPRIETARY ARTICLE CERTIFICATE

TO WHOM IT MAY CONCERN

This is to certify that the following product is a

proprietary product of Baxter: Brand Name: Prismaflex

8.10
Generic Name: Prismaflex 8.10

The above product is manufactured at:

Gambro Lundia AB
Box 10101, Magistratsvagen 16
SE-220, 10 Lund
Sweden

Marketed in India by wholly owned subsidiary:
M/s Baxter (India) Private Limited,
Gala No. 1 to 6, Building No. C15,
Ground Floor, Shree Arihant Complex, Kalher,
Bhiwandi, Dist. Thane,
Tal: Bhiwandi (Thane - Zone 5) – 421302

Legitimate representative of the legal manufacturer

Sincerely,

Signature

2019-05-28
Date

Lund
Place

Marco Toppino
Plant Manager
Gambro Lundia AB

Gambro Lundia AB (including all direct and indirect subsidiaries) is now part of Baxter International Inc.

Specifications for CRRT Machine for Department of Pediatrics, AIIMS Jodhpur

(On Proprietary basis)

Modality Options

- To provide at least 24-hour continuous (nonstop) dialysis therapy used to support patients with kidney failure
- The Machine should be of latest technology with microprocessor controlled user interactive menu with operating and malfunction removal instructions on display screen
- System should be able to perform- CRRT, SCUF ,CVVH Pre and/or Post , CVVHD, CVVHDF Pre or Post, TPE and Hemoperfusion
- Anticoagulation: Syringe, Citrate/Calcium
- Therapeutic plasma exchange, Hemoperfusion, MARS
- Provision to use lactate based dialysate solution and bicarbonate solution simultaneously for CVVHDF therapy
- Provision for recirculation mode
- Provision to enable for sepsis treatment with compatible filter
- **Should be compatible with various size filters ranging from 0.2 msq, 0.6 msq and 0.9 msq (HF 20, HF 60 and HF 100)**
- **Should also be compatible with M10, M60, M100, M150 membranes of AN69 Type.**
- Provision to enable low weight compatible set for CRRT treatment of babies e.g. 8 Kg weight

Electrical Circuit Requirements

- Should have automatic on/off facility with LED indicator on front panel for status of machine
- Supply 100-240 +/- 10% vac, 50/60 Hz fitted with Indian Plug
- Maximum power consumption<600 W
- Normal average power consumption upto 150 W
- Input line current: 5A max rms at 100 Vac, 2.5 A max rms at 240 Vac
- Management of electrostatic charges to avoid ECG interference
- Full battery back up enables continuous treatment delivery for at least 10 min

Flow Rate Ranges

- System should have five pumps, one each for Blood, Dialysate, Replacement fluid and Effluent/filtrate and Regional Citrate

- Blood: 10-450 ml/min

Increment: 2-10 ml/min

Accuracy: +/- 10% of user set rate (at nominal blood flow of 450ml/min or the highest achievable disposable blood flow, having 37 degree Centigrade, at an access pressure of -200 mm Hg and without any PBP Flow)

- Replacement: 0-8000 ml/h

Increment: 50ml/h

- Dialysate: 0-8000 ml/h

Increment: 5-10 ml/h

- Pre blood Pump(pbp): 0 to 4000 ml/h

Increment: 2-50 ml/h

- Patient Fluid removal: 0-2000 ml/h, Effluent pump flow rate- 0-10000 ml/hr

Increment: 5-10 ml/h

Fluid control

- System should have 4 weighing scales with weighing capacity of at least 5 kg for monitoring of the volumes of the total filtrate, replacement fluid and dialysate.

Scale may range from: 0-11 kg
7 g deviation for a solution bag of 5200 g (equivalent to 0.14%)

- Provision for simultaneous delivery of pre and post filter replacement solution in CVVH and CVVHDF therapies

Anticoagulation Options

- Provision for Regional Citrate Anticoagulation for all CRRT therapies.
- Following options for anticoagulation should also be available:

-Systemic, integrated syringe pump
-Regional Citrate-Calcium, external pump
-Regional Citrate- Calcium, integrated syringe pump
-No anticoagulation

Anticoagulation syringe pump

- Systemic integrated syringe pump anticoagulation method: Provision of changing syringe size. Syringe volume range: 20,30 and 50 ml with luer lock
- Continous delivery rate range:

0, or 0.5 ml/h to 5 ml/h for 20 ml syringes
0, or 0.5 to 10ml/h for 30 ml syringes
0, or 2.0 to 20 ml/hr for 50 ml syringes
Increment: 0.1 ml/h

- Bolus Volume range:

0.5 to 5 ml for 20 ml syringe
1 to 5 ml for 30 ml syringes
2 to 9.9 ml for 50 ml syringes

- Regional citrate- Integrated syringe pump anticoagulation method:

- System should have short preparation and priming program and should be ready to start treatment within 10-20 minutes
- Should have Fully integrated and preconnected sets that can be automatically loaded primed and tested
- Should have Touch screen 10-15 ", color TFT-LCD screen that provides all relevant treatment data (Prescription, flows, pressures) with adjustable brightness
- The equipment shall be able to monitor and display the parameters- Arterial pressure, Venous Pressure, TMP, Replacement flow rate, dialysate flow rate, ultrafiltration rate, temperature, Treatment therapy's set time, elapsed time and remaining time, continuous anticoagulation rate and anticoagulation by bolus
- Memory stores up to 96 hours of treatment data
- Optimized deareation chamber avoids blood –air interface
- Small extracorporeal blood volume (60-189 ml depending on the set combination)
- Integrated on-screen guidance for Hemoperfusion, MARS and TPE therapy set up
- Built in dosage calculator
- Software controlled pinch valves allows selection of pre and/or post dilution ration that can be modified during treatment
- Emergency hand crank to be provided for returning blood to patient in case of power failure

- System should have capability of changing therapies without interrupting the treatment

Should have preloaded pediatric module for use in children/infants weighing below 10 kg
System should operate with a low extracorporeal blood volume which is equal or less than 158ml (60 ml for Pediatric) in order to improve patient tolerance without affecting patient's hemodynamic stability and limited blood loss
Should be updated with the latest software both for infant/pediatric as well as adult use.
Provision to upgrade software

Accessories: Blood warmer to maintain Patient temperature
Blood Warmer temp range in increments of 0.5 degree C

External connections:
Equipped with RS232/USB output for PC connectivity and Data acquisition
Remote alarm connection

Physical aspects:

- The unit shall be capable of being stored continuously in ambient temperature of 0-50deg C and relative humidity of 15-90%
- The unit shall be capable of operating continuously in ambient temperature of 10 -45 deg C and relative humidity of 15-90%
- Height: 163cm, width: 49 cm, Depth: 40 cm
- Floor space: 70 × 70 cm

Syringe volume range: 50 ml with luer lock
Calcium delivery rate range: 0 or 2.0 to 1000 ml/h
Calcium concentration range: 80-1000 mmol/l

Safety systems

- Should have closed blood circuit to prevent air to blood interface Ultrasonic air detector: detects single air bubble >20 µl

- Integrated barcode reader to automatically identify loaded treatment set
- The system shall incorporate a self-diagnostic program which upon start up, detect and clearly indicate any defects or malfunction
- The system should be able to perform a self-testing during treatment automatically in a fix period of time not less than one hour to ensure all the components are working properly
- System should have Alarms (Audio and Visual) in case of power failure, equipment malfunction, air in line, blood leak, arterial/venous pressure out of limits, empty dialysate/replacement bag, full effluent bag, TMP out of limit and filter clotting. Integrated alarm management for audible and visual alarm signals with on-screen guidance
- The system should have leak sensor to detect the blood or fluid loss due to loose connection or leakage to avoid the volumetric error.

Blood leak detector:
Leak >0.35 ml/min at 0.25 Hct , for effluent flow rate below 5500 ml/h
Leak >0.50 ml/min at 0.32 Hct , at highest effluent flow rate
Fluid leak detector: Detects fluids greater than 50 ml

- System shall comply with IEC 60601-2-16 Safety requirements particularly for the safety of CRRT equipment

Pressure monitoring:

- Equipped with independent Pre filter pressure sensor

Pre filter pressure: -50 to +450 mm Hg, accuracy: +/- 15 mm Hg
Access pressure: -250 to +450 mm Hg, accuracy: +/- 15 mm Hg

- Equipped with independent Blood return pressure sensor

Return pressure: -50 to +350 mm Hg, accuracy: +/- 5 mm Hg

- Equipped with independent Effluent pressure sensor

Effluent pressure: -350 to +400 mmHg, accuracy: +/- 15 mm Hg

- The system should have patient loss and gain safety limit to avoid the patient excessive fluid loss or gain

- Equipped with independent Pressure sensor port for future therapy e.g couple filtration

Features

- Weight: approx. 80 kg or less
- All materials used for the construction of the system shall be rust proof
- The system shall be easy to clean, disinfect and/or sterilize, as appropriate

Accessories

- The offer shall be completed with all necessary accessories which are essential for the normal operation of the equipment.

- The successful tender shall be keep reasonable stock level for normal necessary consumable items.
- Should be supplied with Nos of essential accessories such as blood line set including dialyzer/circuit with cassette 3 each in no. (0.2 & 0.6 each), ~~and ultra filtrate bags 50 in no. (5L Prismasol)~~ **at no extra cost.**
- All media and consumables for setting up and standardization should be provided free of cost in addition to the items supplied in above mentioned point.
- All spare parts and consumables should be available with the supplier for a period of at least 5 years after commission

Operation Training:

- The successful tender shall be providing the operation program to end user.

Installation:

- Supplier to perform installation, safety and operation checks before handover
- The successful tenderer shall be responsible for the installation of the equipment.
- User/Technical/Maintenance manuals to be supplied in English
- Certificate of calibration and inspection. List of Equipment's available for providing calibration and routine Preventive Maintenance Support as per manufacturer documentation in service/technical manual.
- List of important spare parts and accessories with their part number and costing.
- Log book with instructions for daily, weekly, monthly and quarterly maintenance checklist.
- The job description of the hospital technician, manufacturer, supplier and company service engineer should be clearly spelt out.
- Training of users in machine operation, trouble shooting aspects and basic maintenance shall be provided

Certification:
Submission of all the certifications and test reports to the buyer along with supplies on demand
Availability of test report/quality assurance report from parent manufacturer
Product should be certified by EU-CE/ US-FDA/ BIS (Certification date, issuing authority and number should be provided)
Conformity to Manufacturer's Certification (copy of the same should be submitted to buyer)

Warranty and service: As admin rules